A systematic review of variables used to assess clinically acceptable alignment of unilateral transtibial amputees in the literature

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Abstract

Objectives: Prosthetic alignment is a subjective concept which lacks reliability. The outcome responsiveness to prosthetic alignment quality could help to improve subjective and instrument assisted prosthetic alignment. This study was aimed to review variables used to assess clinically acceptable alignment in the literature.

Methods: The search was done in some databases including: Google Scholar, PubMed, EBSCO, EMBASE, ISI Web of knowledge and Scopus. The first selection criterion was based on abstracts and titles to address the research questions of interest. The American Academy of Orthotics and Prosthetics checklists were used for paper risk of bias assessment.

Result: Total of 25 studies were included in this study. Twenty-four studies revealed the critics of standing position or walking to locate clinically acceptable alignment, only one study measured outcomes in both situations. Total of 253 adults with transtibial amputations and mean age of 48.71 years participated in included studies. The confidence level of included studies was low to moderate, and before-after trial was the most common study design (n=19).

Conclusion: The joint angle, load line location with respect to joints and COP related parameters were reported as sensitive outcomes to prosthetic alignment quality in standing posture. The amount of forces at various parts of gait cycle and time of events were sensitive to prosthetic alignment quality during walking.

Clinical relevance: Standing balance and posture and temporal parameters of walking could help to locate clinically acceptable alignment.

Keywords: COP, temporal-spatial, kinetic, kinematic, clinically acceptable alignment, transtibial prosthesis,

Introduction

Prosthetic alignment is a key part of lower limb prosthetic fitting, and is defined as the relative spatial position of prosthetic components to socket and amputee's anatomical segments (1). In current clinical practice, prosthetic alignment is assumed to be optimum when a) no obvious gait deviation is seen by a prosthetist and b) the prosthesis is considered comfortable by the user. In a 2 body system, like a transtibial prosthesis (where foot and socket are the 2 bodies of interest), there are 6 degree of freedom (3 in translation, 3 in rotation) that describe all possible orientations of the parts with respect to each other. Prosthetic alignment is a time consuming process which depends on experience of prosthetic user and the practitioner and lacks inter- and intra-rater reliability (2). Previous studies have shown that final optimal alignment may considerably vary (2, 3).

The subjective perception of the amputee and practitioner is the most frequent criterion to uphold acceptable alignment assessment in clinical situations (2, 4). Although the sagittal socket alignment could affect socket reaction moment in both of sagittal and frontal planes, the amputee's perception from prosthetic alignment is less reliable in this plane (5-7). Though in clinically acceptable alignment prosthetic foot is aligned toward an invariant roll-over shape, it is unclear that the shape would match to that of a healthy physiologic system (8). There are many significant biomechanical differences between sound and prosthetic limbs even in clinically acceptable alignment (9-12). The prevalence of hip and knee osteoarthritis is significantly higher at lower limb amputees, particularly sound side of unilateral amputees is significantly more subjected (13-17); improper prosthetic alignment could worsen the risk (18). Practitioners have a critical need to evidence on relationship between alignment and outcomes responsiveness, which would help for objective prosthetic alignment (1).

Lots of studies have tried to determine clinically acceptable alignment through quantifying the biomechanical effects of prosthetic alignment adjustment. The clinically acceptable alignment is not the optimal situation for all lower limb muscles (16). The prosthetic alignment adjustment may lead to significant changes in muscle activity pattern, walking symmetry, standing balance, energy expenditure, muscle activity of lower limbs and sub maximum tissue loading of residual limb, pain and potential tissue breakdown (11, 12, 15-17, 19-24). The outcome measure condition and the value, direction and component of prosthetic alignment adjustment differ in various studies; it is unclear that how each prosthetic alignment adjustment could affect the amputee biomechanics.

The objective of the current study was to review variables used to assess optimal alignment in the literature systematically. This would help to access the responsiveness of various outcomes to prosthetic alignment which would help to improve subjective and instrument assisted prosthetic alignment.

Methods

The search was done from the beginning of electronic databases until 05/2017 in some databases including: Google Scholar, PubMed, EBSCO, EMBASE, ISI Web of knowledge and Scopus. The search key words were below knee or transtibial amputee, prosthetic alignment, kinetic, kinematic, interface pressure, plantar pressure, balance, electromyography, validity and reliability. We followed the steps and guideline suggested by Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) (25)

The first criteria to select the papers was based on the following items: 1) studies examining properties of the optimal or clinically acceptable alignment, 2) measuring the outcomes for the optimal or clinically acceptable alignment, 3) evaluating validity/ reliability/ accuracy/ sensitivity/ repeatability of any alignment device/s used for measuring alignment changes or alignment adjustment on unilateral or bilateral transtibial amputees and 4) with any cause of amputation. The exclusion criteria were papers on amputation level other than transtibial, participants with less than 6 months of prosthetic use (i.e., immature residual limb), sample size less than 5 and papers in languages other than English were excluded (figure 1). After deleting duplicated records, two reviewers evaluated title and abstracts of records based on inclusion criteria. Then, both reviewers evaluated full texts of included studies as stated in figure 1. To avoid influential bias, each reviewer did the process independently. Also, papers which were cited in other papers and not reported in search results were added.

The data extraction table were prepared using the available forms such as the form provided by the Cochrane data collection and form for non-randomized studies (26). The American Academy of Orthotists and Prosthetists (AAOP) checklist of internal and external validity were used to access risk of bias (27). The form includes 18 potential threats to internal validity and eight potential threats to external validity that must be assessed for each article (Appendix A). Risk of bias was assessed by the first (N.T) and the second reviewer (F.H). Though there were some disagreements, the reviewers checked the risk of bias within studies by consensus strategy. The validity of studies assumed as low, moderate and high with regard to confidence level could be undertaken on findings of the investigation (28).

Results

A total of 37 studies were selected for systematic review. To avoid ambiguity and elongation, the studies were put in two groups: I) papers used variables to assess optimal alignment, II) papers define “acceptable prosthetic alignment”. Evaluation of group I is the subject of current paper and the group II would be described in another paper. Twenty-five studies were included to this study. Selection of papers is stated in the flow diagram (figure 1).

Characteristics of Included Studies

Study design. Most of studies were before-after trial (about 76 %) (table 1). The majority of studies were on small samples (e.g. <15). The details of study design and sample size is stated in the table 1**.**

Subject Characteristics. A total of 253 adults with transtibial amputations and mean age of 48.71 years participated in the included studies. Most of the participants were male (n=184), less were female (n=28) and the sex of 41 participants was not stated. The cause of amputation was mostly trauma (n= 126), other reasons were peripheral vascular disease (n=25), tumor (n=1) and infection (n=2); the cause of amputation was not specified for 99 participants.

Intervention. Twenty-three studies analyzed the effects of prosthetic alignment adjustments (tables 2 and 3). The sagittal prosthetic foot or shoe alignment was changed in six studies (4, 15, 17, 20, 23, 30). The sagittal socket alignment was changed in one study (29). The effect of sagittal and frontal prosthetic alignment adjustments were analyzed in twelve studies (5-7, 9, 10, 16, 21, 31-35). The transverse prosthetic foot rotation was changed in three studies (11, 12, 36). Only one study analyzed the effects of prosthetic alignment adjustments in all plane (22).

Comparison. The subject of 2 studies was analyzing outcomes in clinically acceptable alignment to better understanding the situation (37, 38) (table 3).

Outcomes. The effects of adjustment on clinically acceptable prosthetic alignment or reports on clinically acceptable alignment with any outcome variables were collected. The data collection of twenty-four were in standing or walking situation. Only one study had data collection in both conditions (23). Therefore, we put studies in two groups: 1) studies with data collection in standing posture and 2) papers with data collection during walking.

Risk of Bias Assessments. Based on the AAOP checklist, there were some recurrent issues affecting both internal and external validity. Issues of concerns for study validity are stated at tables 4 and 5 (based on AAOP assessment criteria, appendix A). Threats concerning internal validity ranged from 9 to 15; threats concerning external validity ranged from 4 to 9. No study was considered to have high quality.

Results Narrative

Due to lack of statement about measuring effect and homogeneity in study design, intervention, participants and outcome measure of included studies, meta-analysis was impossible. Therefore, a qualitative synthesis of results was performed.

Data collection in standing situation

Standing balance

Four studies reported the effects of prosthetic alignment adjustment on standing balance parameters. Luengas et al. reported that (±2°, 4° and 6°) sagittal socket adjustments changed the center of pressure (COP) location in prosthetic limb and the vertical component of COP showed significant correlation with socket position (29). The study also showed lower limb joint angle is a sensitive parameter to prosthetic alignment. Jia et al. reported by increase of heel height COP displaced toward forefoot, peak pressure increased at medial forefoot and decreased at hind foot but did not change at lateral border of forefoot (30). Janura et al. analyzed the effects of ± 5° of sagittal foot tilt and ±1cm change of prosthesis length on standing balance (31). They found extra plantar flexion and 1cm lengthening decreased stability of sound limb significantly (31). Kolarova et al. analyzed the effects of ± 5° of sagittal foot tilt and ±1cm change of prosthesis length on stability parameters (21). They found significant decrease of end point excursion due to 1cm shortening and dorsiflexion adjustments (21).

Electromyography

Three studies reported the effects of prosthetic alignment adjustment on electromyography parameters. Jia et al. reported increase in the mean absolute value of EMG of rectus femuris, vastus medialis and lateralis and both heads of gastrocnemius muscles at prosthetic limb by increase of heel height from zero to 40 mm (15, 30). However, the activities of the same muscles on sound limb did not change a lot. Paráková et al. analyzed the effects of ±5° sagittal adjustment of foot and ±1cm change of prosthesis height on muscle activity, and selected posturographic parameters (16). Medial head of gasterocnemius, biceps femoris and tibialis anterior muscles of sound side were sensitive to adjustments (16).

Perception

Boone et al. analyzed amputee’s perception from alignment adjustment by means of visual analogue scale and simultaneous evaluation of socket reaction moment (7). They found amputee's perception is a consistent indicator of mal-prosthetic alignment in all cardinal planes, but was less reliable in sagittal and transverse planes ($p<0.001$ and $p<0.05$, respectively).

Stump-socket interface pressure

Seelen et al. analyzed the effects of 0.5cm wedge to forefoot and heel on interface pressure during standing and walking (23). Sagittal adjustments had an inverse (un-) loading effect on sub-patellar region versus distal tibia and changed sub-maximal tissue loading of residual limb but did not have any significant effect on fibular head region (23).

Data collection in walking situation

Spatiotemporal gait parameters

Chow et al. analyzed symmetry of kinetic and spatiotemporal gait parameters in all acceptable alignments of each case (38). Although the locations of the most symmetric alignments had no obvious similarities in subjects, six parameters were consistently less asymmetric in all acceptable alignments (table 3).

Five studies reported the effects of prosthetic alignment adjustments on spatiotemporal gait parameters (table 3). Fiedler et al. reported addition of 2° of foot plantar flexion would increase step length symmetry at low exertion levels; after increasing physical exertion level addition of 2° of foot plantar flexion increased the step length asymmetry significantly with respect to same condition at low exertion levels (20).

Two studies compared three conditions of clinically acceptable alignment, 6° of extra internal rotation and external rotation; participants of both studies reported the internal rotation as less comfortable (11, 12). Fridman et al. investigated the effects of 18° and 36° of extra external rotation of prosthetic foot on kinematic parameters (36). Only 36° of external rotation had significant effects (table 2). VanVelzen et al. analyzed the effects of ±15° adjustment of socket angle in all three planes on kinetic of amputated side and spatiotemporal parameters of walking (22). Only the socket external rotation experienced significant effects (table 2).

Kinetic parameters during walking

Eight studies reported the effects of prosthetic alignment adjustment on kinetic parameters. Pinzur et al. reported ±10° angular change of socket tilt in both anterior-posterior and medial-lateral direction had no significant effect on kinetic and kinematic parameters (9). Fiedler et al. analyzed the correlation of subjective perception of amputees and objective effects of ±3°, 6° and 9° sagittal foot adjustments on step by step variability of ground reaction force during walking (4). The amputee's perception was significantly correlated to prosthetic alignment quality. However, step by step variability showed weak correlation to these variables (4).

Kobayshi et al. analyzed out-of-plane and in-plane effects of improper alignment on socket reaction moment in six studies. They found that both angular and translational changes have some significant out-of-plane and in-plane effects (table 3) (5, 6, 32, 35). They reported significant effects of prosthetic alignment adjustment in sagittal and frontal planes on forces and moments at base of the socket (referred as socket reaction moment) at various parts of the stance phase (33). Frontal plane adjustments were mostly compeer with changes of varus socket reaction moment impulse (6). However, another study showed that the effects of same adjustment on socket reaction moment may be less consistent between amputees (34). The effects of adjustments on socket reaction moment in sagittal plane were more complex.

Plantar pressure

Geil et al. analyzed plantar foot pressure during dynamic prosthetic alignment (37). In non-optimal alignment of frontal plane plantar pressure shifted toward lateral border of sound limb; the effects of sagittal prosthetic alignment changes were less uniform (37).

Energy expenditure

Schmalz et al. analyzed the effects of 10° sagittal foot tilt and 2cm displacement of foot to anterior and posterior on biomechanics of walking and oxygen consumption during treadmill walking (17). Angular foot adjustments changed duration of action of sagittal moments, maximum sagittal moment at second half of stance phase and had significant effect on oxygen consumption.

Walking stability

Rossi et al. reported the effects of sagittal and frontal planes prosthetic alignment adjustment on gait initiation parameters (10). They reported sagittal and frontal foot alignment adjustment had no statistically significant effect on gait initiation parameters (10).

Discussion

The primary objective of the present systematic review was to review variables used to define clinically acceptable alignment. Studies low confidence on internal validity and moderate confidence on external validity revealed the COP related parameters and joint angle as sensitive outcomes to prosthetic alignment quality in standing position and the outcomes of socket reaction moment at various stages of stance phase, impulse of socket reaction moment and the time of moment action during walking as sensitive to prosthetic alignment during walking. Prosthetic alignment parameters related to socket and extra anteroposterior tilt and internal rotation of prosthetic foot were more affective. Four studies measured the COP related parameters in standing posture, with no controversy, they reported sensitivity of these parameters to improper prosthetic alignment (21, 29-31). The socket alignment was significantly correlated to vertical component of COP (29). The sagittal prosthetic foot alignment could affect standing stability and change COP location (21, 30, 31). The sagittal prosthetic alignment could also change sagittal angle of hip and knee joints, load line location and the muscle activity around knee joint in standing position (29, 30). Parakova et. al. stated that when prosthetic length was extended about 1 cm weight bearing was more symmetric between two limbs (16). As a whole, a more robust study reported that in clinically acceptable alignment, with equal limb length, the weight bearing should be equal between two limbs (29). Therefore, evaluation in standing position could provide many critical information regard to prosthetic alignment quality.

With low internal validity and moderate external validity, the impulse of socket reaction moment and socket reaction moment at 30% and 75% of stance phase were sensitive to angular and translational changes of prosthetic alignment (6, 32, 35). With a higher level of validity, excessive or insufficient shoe heel height may increase residual limb loading duration during walking (23). Angular changes of prosthetic in the sagittal plane on had statistically significant effects on the oxygen consumption; however, the adjustment had not significant effects on spatial gait parameters such as walking speed, walking cadence and symmetry of ground reaction force (17, 20). Parameters such as duration of action of flexion or extension moments, maximum knee extension moment at the second half of stance phase and step duration were sensitive to prosthetic alignment quality (4, 17). Therefore, both of evidences with moderate level of confidence and lower, revealed time related characteristics of kinetic and kinematic gait parameters are more sensitive to prosthetic alignment quality than spatial gait parameters.

With moderate level of confidence symmetry of some gait parameters such as first and second peak of vertical ground reaction forces, minimum of vertical ground reaction force between two peaks, stance duration, step length and time to maximum flexion during the swing phase was stated to be higher at the clinically acceptable alignment (11, 12, 38). However, with similar level of confidence, Fiedler et. al. reported the effects of sagittal foot angle on kinetic and kinematic parameters may vary (20).Some evidences with low internal validity and moderate external validity supported the sensitivity of duration of action of sagittal moments or the amount of moments at various parts of stance phase to sagittal prosthetic alignment quality (17, 35). The significant effects of internal foot rotation on kinetic parameters of hip and temporal gait parameters was also reported (11, 12). The usefulness of kinetic and kinematic gait symmetry to locate clinically acceptable alignment had some controversies.

With low confidence level, prosthetic alignment quality did not show any significant effects on gait initiation, step-by-step variability, vertical component of ground reaction force, impulse and stance phase duration during walking (4, 9, 10). It may be due to adaptation to mal prosthetic alignment or walking with self-selected velocity (39). With better level of confidence, evidences reported the effects of prosthetic alignment adjustments were more visible at higher walking velocities, walking cadence was also sensitive to prosthetic alignment adjustment (5, 17, 20). An evidence with low confidence level reported 10° of sagittal adjustment had no significant effect on ground reaction force impulse during walking with self-selected cadence; however, an evidence which was excluded from this systematic review reported only 4° of foot anterior tilt changed ground reaction force impulse significantly for fast running amputees (9, 40). The responsiveness of kinetic outcomes to prosthetic alignment quality may need to data collection with higher walking speed instead of self-selected walking speed which needs more investigation.

The validity of included studies was considered as low to moderate. About 76 % of included studies were uncontrolled before-after trial, and the design was intrinsically weak. There was no randomized control trial, the sampling method of all participants was sampling of convenience method. The inclusion criteria were not reported in majority of studies and some others had not proper inclusion criteria due to broad amputation etiology or age range. About 80% of studies had no statement on exclusion criteria or had improper exclusion criteria due to improper socket fit quality or ignoring it and the possible existence of gait pathologies. In addition, the sample characteristics were not adequately described in fourteen studies. The sample size of 88% of studies were less than 15 participants, the participants of three studies were limited to experienced amputees and use of conventional foot and liners were also common.

Blinding was mentioned only by two studies, which their intervention were blinded to participants only (4, 7). Lack of blinding affects the consistency, value of outcome assessment and internal validity (41). Though, exhaustion could alter the kinematics of amputee walking, the protocol of about 84% of included studies did not notice to fatigue (42). However, most of studies randomized the intervention order which substitutes the lack of blinding and tiredness of participants somewhat. Lack of outcome measure reliability was concerned with all of studies. The nominally clinically acceptable alignment seems to replicable only in two studies (17, 38). Although prosthetic alignment is a subjective concept, only two study reported the subjective statements of prosthetist and amputee about prosthetic alignment (4, 7). The measurement tool calibration is specified at three study protocols (29, 35, 38). Seven studies had statements about the quality of instrumentation (4, 5, 20, 29, 32, 33, 38). Therefore, the internal validity, instrument reliability and comparison to gold standard was unclear.

An accurate judgement on socket fit and prosthetic alignment quality needs to an acclimation period. The recommended adaptation time is not consistent between studies. For example Safari et al designated the adaptation time to a new prosthesis as 2 weeks or more (43). Though the AAOP check list was used for quality assessment with current study, the adaptation time to a new prosthetic alignment adjustment assumed to be more than 5 minutes (28, 44). The protocol of 64% of included studies did not mention about adaptation time to prosthetic alignment adjustment and the adaptation time of 5 studies was 5 minutes or less. The statistical analysis of included studies were student t-test, ANOVA, MANOVA and non-parametric tests. Four studies had no statement about the used statistical analysis (6, 12, 32, 35). The objective measure of various measurements should be consistent, which could be assessed by reliability analysis (45). However, the study protocol of many participants did not address this. Though statistical significance is at least of interest and does not support the clinical significance, it was the most common reported result (46, 47). No analytical study reported statistical power and the effect size which emphasizes the effects of size of differences on results.

All of studies were concerned with threats to clinical relevance or significance of findings. The most common threat was lack of recommendation regard to acceptable alignment. High cost of instrumentation in majority of studies was another threat for clinical relevance of reports. The results of four studies contradicted to previous studies or result of same study (4, 16, 29, 36). For example, the prosthetic alignment adjustment led to significant increase of stance time and decrease of step length of sound limb at the same time (36). Due to threats related to validity of included studies, confidence on results should regard cautiously.

Conclusion

Twenty-five studies included to this systematic review. The confidence level was low to moderate. The joint angle, load line location with respect to joints and COP related parameters were sensitive to prosthetic alignment quality in standing posture. The amount of forces at various parts of gait cycle and time of events were sensitive to prosthetic alignment quality during walking.

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Declaration of Conflicting Interests

The Authors declare that there is no conflict of interest.

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Table 1: Demographic characteristics of included studies

		First Author	Setting	Design	IV*	EV**	n	Years Since Amputation
Outcome measure in standing	1	Luengas (29)	Hospital Militar Central, Colombia	One grouped before after trial	Low	Moderate	7	NS
	2	Seelen (23)	Outpatient clinic, Netherlands	One grouped before after trial	Moderate	Moderate	17	NS
	3	Jia (15)	Laboratory, China	Case series	Low	Low	5	6.8
	4	Jia (30)	Laboratory, China	Case series	Low	Low	5	6.8
	5	Janura (31)	Laboratory, Czech Republic	One grouped before after trial	Low	Moderate	13	NS
	6	Kolarova (21)	Laboratory, Czech Republic	One grouped before after trial	Low	Moderate	10	NS
	7	Paráková (16)	Laboratory, Olomouc	One grouped before after trial	Low	Moderate	13	11.5
	8	Boone (7)	Clinic hallway, China	One grouped before after trial	Low	Moderate	11	NS
Outcome measure during walking	9	Schmalz (17)	Department of Research, Germany	One grouped before after trial	low	Moderate	7	23
	10	Fiedler (20)	Laboratory, USA	One grouped before after trial	Moderate	Moderate	8	NS
	11	Fiedler (4)	Clinic hallway, USA	One grouped before after trial	Moderate	Moderate	12	NS
	12	Pinzur (9)	Laboratory, USA	One grouped before after trial	Low	Low	14	NS
	13	Rossi (10)	Department of Orthopaedic Surgery, USA	One grouped before after trial	Low	Low	7	NS
	14	Boone (32)	Orthocare Innovations, USA	One grouped before after trial	Low	Moderate	11	NS
	15	Kobayashi (5)	Orthocare Innovations, USA	One grouped before after trial	Low	Moderate	11	NS
	16	Kobayashi (33)	Orthocare Innovations, USA	Case series	Low	Moderate	11	NS
	17	Kobayashi (34)	Orthocare Innovations, USA	Case series	Low	Low	10	NS
	18	Kobayashi (35)	Orthocare Innovations, USA	One grouped before after trial	Low	Moderate	11	17
	19	Kobayashi (6)	Orthocare Innovations, USA	One grouped before after trial	Low	Moderate	10	17
	20	Fridman (36)	Laboratory, Israel	One grouped before after trial	Low	Moderate	8	13.5
	21	Beyaert (11)	Laboratory, France	One grouped before after trial	Low	Moderate	17	16.7
	22	Grumillier (12)	Laboratory, France	One grouped before after trial	Low	Moderate	17	NS
	23	VanVelzen (22)	Laboratory, Netherlands	One grouped before after trial	Low	Moderate	5	21
	24	Geil (37)	Atlanta, Georgia, USA	Case series	Low	Moderate	6	13.16
	25	Chow (38)	Department of Health Technology and Informatics, China	Cross sectional study	Moderate	Moderate	7	11

Abbreviations: *IV: Internal Validity; **EV: External Validity, NS: Not specified

Table 2. Summary of studies with data collection in standing position

Plane (s)	Adjustment Description		First author	n	Selected outcome variables		Mean (S.D) at clinically acceptable alignment	Result summary
Sagittal	±[2°, 4°, 6°] (sagittal socket angle)	1	Luengas (29)	7	X component of COP (mm)	Sound limb	55.7 (1.9)	The adjustments caused statistically significant changes of the joint angles and COP in the antero-posterior direction. The adjustment also increased loading on sound limb.
						Prosthetic limb	28.9 (1.5)	
					Y component of COP (mm)	Sound limb	95.9 (19.09)	
						Prosthetic limb	138.7 (14.14)	
					Knee joint angle	Sound limb	2(1.43	
						Prosthetic limb	2.16(3.88	
	Heel and forefoot wedge (0.5 cm)	2	Seelen* (23)	17	Mean peak stump/socket interface pressure (in % body weight/cm2)	Subpatellar	23 (0.05)	By addition of heel wedge submaximal tissue loading significantly decreased at the end of tibia and increased in patellar tendon region, the effects of forefoot wedge was the opposite on same regions.
						Tibia end	0.20 (0.04)	
						Fibular head	0.20 (0.03)	
					Mean pressure level over 80% of peak pressure	Subpatellar	0.53 (0.09)	
						Tibia end	0.63 (0.11)	
						Fibular head	0.62 (0.14)	
					time percent in which pressure exceeded 80% of peak pressure	Subpatellar	20.6 (3.9)	
						Tibia end	24.3 (3.6)	
						Fibular head	31.3 (3.6)	
	Shoe heel height of zero, 20 mm and 40 mm	3	Jia (15)	5	mean absolute value of EMG of 4 muscles of both sides		Not specified	By increasing heel height to 40 mm, the activity of knee extensors at prosthetic limb increased.
		4	Jia (30)	5	mean absolute value of EMG (same as stated at row 6), plantar pressure, load line location		Not specified	All outcomes were affected by the adjustment. At the heel height of 20 mm the outcomes were optimal.
Sagittal and frontal	± 5° (sagittal foot angle), ±1 cm (prosthesis length)	5	Janura (31)	13	Fluctuation of COP in medio-lateral and anterior-posterior directions		Not specified	Plantar flexion and 1cm lengthening increased load distribution on sound limb and load differences between two limbs exceeded physiological limit
					Area of the confidence ellipse			
		6	Kolarova (21)	10	Anterior direction	End point excursion %	59.9 (18.32)	5° of foot posterior tilt changed the endpoint excursion in backward direction significantly; the adjustment was more effective than changing prosthetic length.
						Direction control %	89.5 (6.88)	
						Movement velocity (°/s)	3.48 (1.80)	
						Reaction time (s)	1.04 (0.43)	
					Posterior direction	End point excursion %	60.7 (16.1)	
						Direction control %	80.71 (9.99)	
					Right direction (prosthetic limb)	End point excursion %	76.11 (10.76)	
						Direction control %	2.48 (0.9)	
						Movement velocity (°/s)	3.72 (1.63)	
						Reaction time (s)	0.86 (0.37)	
					Left direction (sound limb)	End point excursion %	79.71 (19.42)	
						Direction control %	86.12(8.13)	
						Movement velocity (°/s)	4.72 (2.05)	
						Reaction time (s)	0.9 (0.36)	
		7	Paráková (16)	13	Latency of motor reactions, reactivity pattern of muscles		Ns	1 cm extending of prosthetic length and 5° of foot posterior tilt changed the latency of postural reactions and muscle reaction time significantly.
	± 3°, 6° (frontal and sagittal socket angles) ± 5 and 10 mm (frontal and sagittal socket translation)	8	Boone (7)	11	The parameters of sensitivity, specificity and likelihood ratio were not special to clinically acceptable alignment		Not applicable	The interventions showed amputees perception is a good indicator of clinically acceptable alignment in frontal plane; however their perception was less reliable in sagittal and frontal planes.
Abbreviation: Vgrf means vertical component of ground reaction force, *This study had two conditions walking and standing for data collection								

Table 3. Summary of studies with data collection in standing position

Plane(s)	Adjustment Description		First author	n	Selected outcome variables		Mean (S.D) at clinically acceptable alignment	Result summary
Sagittal	± 10° (sagittal foot angle), ± 2cm (sagittal foot translation)	1	Schmalz (17)	7	Stride length		0.73 (0.05)	10 degree of extra dorsiflexion led to significant increasing of oxygen consumption
					O2 rate at speed of 4 kmm/h		13.9 (1)	
					O2 rate at speed of 4.8 kmm/h		16.3 (1.6)	
					Knee extension moment		Not specified	
	± 2° (sagittal foot angle)	2	Fiedler (20)	8	step length, stance phase duration, flexion angle (knee, ankle), flexion moment (knee, ankle), rotation moment, pelvis tilt, and pelvis obliquity.		Not specified	The effects of intervention on symmetry of kinematic and kinetic parameters were inconsistent
	±[3°, 6°, 9°] (sagittal foot angle)	3	Fiedler (4)	12	Perceived prosthetic alignment quality, step variability, peak GRF in horizontal plane, axial torsion moment		Not specified	Step by step variability had weak correlation to amputee's perception and alignment quality
Sagittal and frontal	±10° (frontal and sagittal socket angles)	4	Pinzur (9)	12	Peak Force	Sound limb	865.37 (15 .6)	The GRF* values of the sound limb were significantly higher than prosthetic limb at clinically acceptable alignment. The intervention had no significant effect on GRF and impulse.
						Prosthetic limb	792.76 (12.3)	
					Impulse	Sound limb	538.57 (10.9)	
						Prosthetic limb	468.93 (7 .62)	
					Stance Time	Sound limb	0.88 (0.10)	
						Prosthetic limb	0.82 (0.08)	
	± 5° (frontal and sagittal foot angles), ± 2 cm (prosthesis length)	5	Rossi (10)	7	Force parameters related to gait initiation		Not specified	The gait initiation parameters significantly differed between sound and prosthetic limbs and the effects prosthetic alignment adjustment on the parameters was not statistically significant.
	± 3°, 6° (frontal and sagittal socket angles) ± 5 and 10 mm (frontal and sagittal socket translation)	6	Boone (32)	11	Minimum moment		-0.15 (0.12)	The adjustments had significant in-plane effects on socket reaction moment in both of sagittal and frontal planes.
					Maximum moment		0.72 (0.18)	
					Moment at 30% of stance phase		-0.08 (0.08)	
					Moment at 75% of stance phase		0.013 (0.05)	
		7	Kobayashi (5)	10	Moment at 45% of stance phase		0.22 (0.14)	3° and 6° of socket anterior tilt changed frontal plane socket reaction moment significantly, but the opposite did not occur.
					Maximum moment		0.72 (0.18)	
					moment at 30% of stance phase		-0.08 (0.08)	
					moment at 75% of stance phase		0.013 (0.055)	
		8	Kobayashi (33)	11	Mean moment-moment interactions when maximum frontal socket reaction moments are observed at early stance	Stance (%)	31	3° and 6° adduction and 10 mm medial translation changed the time of peak frontal socket reaction moment.
						Frontal moment (Nm)	-0.08 (0.08)	
						Sagittal moment (Nm)	- 0.034 (0.16)	
		9	Kobayashi (34)	11	Maximum sagittal moment (Nm/kg)		108.91 (15.61)	The correlation of maximum sagittal moment and cadence was statistically significant at clinically acceptable alignment
					Cadence (step/ minute)		0.72 (0.18)	
	± 2°, 4°, 6° (frontal and sagittal socket angles) ± 5, 10 and 15mm (frontal and sagittal socket translation)	10	Kobayashi (6)	10	Valgus moment impulse (Nm.s/kg)		0.0032 (0.0039)	Angular and translational prosthetic alignment adjustments had significant in-plane effects on socket reaction moment impulse.
					Varus moment impulse (Nm.s/kg)		-0.03 (0.017)	
					Extension moment impulse (Nm.s/kg)		0.17 (0.051)	
					Flexion moment impulse (Nm_s/kg)		-0.0090(0.02)	
		11	Kobayashi (35)	10	Moment at 45% of stance phase		0.25 (0.16)	The sensitivity of moments to adjustments in sagittal and frontal planes varied at each quarters of stance phase
					moment at 30% of stance phase		−0.081 (0.06)	
					moment at 75% of stance phase		0.046 (0.082)	
	18°, 36° (foot external rotation)	12	Fridman (36)	8	Stance time	Sound limb	0.78 (0.09)	Only 36° of extra external rotation led to significant decrease in stance time, increase in swing time and step length of
						Prosthetic limb	0.77 (0.08)	

Plane(s)	Adjustment Description		First author	n	Selected outcome variables		Mean (S.D) at clinically acceptable alignment	Result summary
					Step length	Sound limb	63.06 (7.08)	prosthetic limb.
						Prosthetic limb	67.36(10.26)	
	± 6° (foot internal or external rotation)	13	Beyaert (11)	17	Stride length (m)	Sound limb	1.51 (0.18)	The uncomfortable foot internal rotation led to significant change of the sound side knee kinematic.
						Prosthetic limb	1.51 (0.19)	
					Single support phase (s)	Sound limb	0.44 (0.03)	
						Prosthetic limb	0.42 (0.03)	
		14	Grumillier (12)	17	Stride length (m)	Sound limb	1.51 (0.18)	The uncomfortable foot internal rotation led to significant change of the kinematic and kinetics of sound side hip joint.
						Prosthetic limb	1.51 (0.19)	
					Single support phase (s)	Sound limb	0.44 (0.03)	
						Prosthetic limb	0.42 (0.03)	
All planes	±15° (frontal, sagittal and transverse pylon angles)	15	VanVelzen (22)	5	Step length	Sound limb	0.72 (0.1)	Socket alignment adjustments revealed some significant effects on GRF and ankle moment.
						Prosthetic limb	0.69 (0.1)	
					Step duration	Sound limb	52.8 (3.4)	
						Prosthetic limb	48.9 (0.9)	
None	None	16	Geil (37)	6	Plantar pressure		Not specified	Frontal shifts in socket alignments caused lateral shift in plantar pressure of sound limb.
		17	Chow (38)	7	Asymmetry index£ of first peak of vertical GRF		0.107	The clinically acceptable alignment was not a unique situation with maximum inter-limb symmetry. Six parameters were consistently more symmetric: first and second peak of vertical GRF, tough of vertical GRF stance duration, step length and time to maximum flexion during the swing phase
					Asymmetry index of tough of vertical GRF		0.068	
					Asymmetry index of second peak of vertical GRF		0.077	
					Asymmetry index of stance duration		0.094	
					Asymmetry index of step length		0.115	
					Asymmetry index of time to maximum flexion during the swing phase		0.271	

*GRF: ground reaction force

£ Asymmetry index: the value assessed by dividing the absolute difference between the values of sound and prosthetic limbs by their mean

Table 4. Threats for internal validity of included studies

		First author	Internal validity														Sum
			6	7	8	9	10	11	12	13	14	15	16	17	18	19	
Outcome measure in standing	1	Luengas (29)	a		b	a	a		NA	a, c, d	a	a		a	a		11
	2	Seelen (23)	a	b, c	b	a	a		NA	a, c, d, e, f		a		a	a		9
	3	Jia (15)	a	a	a	a	b	NA	NA	a, c, d, e, f	NA	NA	NA	NA	a	a	12
	4	Jia (30)	a	a	a	a	a	NA	NA	a, c, d, e, f	NA	NA	NA	NA	a		11
	5	Janura (31)	a	a	a	a	a	NA	NA	a, c, d, e, f	a	a		a	a	b	15
	6	Kolarova (21)	a	b, c	b, c	b		NA	NA	a, c, d, e, f	a	a		a	a		15
	7	Paráková (16)	a	a	a	a	a	NA	NA	a, c, d, e, f	a	a		a	a		14
	8	Boone (7)	c		a	a	a	NA	NA	a, b, e, f	a	a		a	a		12
Outcome measure during walking	9	Schmalz (17)	a	a	b			NA	NA	c, d, e, f		a		a	a		10
	10	Fiedler (20)	a	b, c		a	NA	NA	NA	a, c, d, e		a		a			10
	11	Fiedler (4)	c	b, c			a		NA	a, e	a	a		a			9
	12	Pinzur (9)	a		b, c, d	a	b	NA	NA	a, c, d, e, f	a	a		a	a	a	15
	13	Rossi (10)	a	a	a	a	a	NA	NA	a, c, d, e, f		a		a	a		13
	14	Boone (32)	a		a	a	a	NA	NA	a, c, d, e	b	a		a	a		12
	15	Kobayashi (5)	a	b, c	a	a	a	NA	NA	a, c, d, e	a	a		a	a		14
	16	Kobayashi (33)	a	a	a	a	a	NA	NA	a, c, d, e	NA	NA	NA	NA	b		10
	17	Kobayashi (34)	a	a	a	a	a	NA	NA	a, c, d, e, f	NA	NA	NA	NA	b		11
	18	Kobayashi (6)	a	a	a	a	a	NA	NA	a, c, d, e, f	b	a		a	b		13
	19	Kobayashi (35)	a	a	a	a	a	NA	NA	a, c, d, f	b	a		a	b		13
	20	Fridman (36)	a	a		a	b	NA	NA	a, c, d, e, f		a		a	a		13
	21	Beyaert (11)	a	b, c		a	b	NA	NA	a, c, d, e, f	a	a		a			13
	22	Grumillier (12)	a	b, c		a	b	NA	NA	a, c, d, e, f	b	a		a			13
	23	VanVelzen (22)	a	a	a	a, b	a	NA	NA	a, c, d, e, f	a	a		a	a		15
	24	Geil (37)	a	a	a	a	a	NA	NA	a, c, d, e, f, h	NA	NA	NA	NA	a	a	12
	25	Chow (38)	a	b, c	a			NA	NA	c, d		a		a	a		9

NA is the abbreviation of not applicable to this study.

Table 5. Threats for external validity of included studies

		First author	External validity								Sum
			1	2	3	4	5	6	7	8	
Outcome measure in standing	1	Luengas (29)			c	a, b	a	b, c		c	7
	2	Seelen (23)				a, b	a	c			4
	3	Jia (15)		b	a	a, b	a	b, c		b	9
	4	Jia (30)	a	b	a	a, b	a	b, c		b	9
	5	Janura (31)	a		a	a, b	a	b			6
	6	Kolarova (21)	a			a, b	a	b, c			6
	7	Paráková (16)	a	a	a	a, b	a	b	b		8
	8	Boone (7)	a	b		b	a	c			5
Outcome measure during walking	9	Schmalz	a	a		a	a	b			5
	10	Fiedler (20)	a	b	a	a	a	c			6
	11	Fiedler (4)		a	a	b		b, c		c	6
	12	Pinzur (9)	a	b		a, b	a	b		b, c	8
	13	Rossi (10)	a	b	c	a, b	a	b, c			8
	14	Boone (32)		b		a	a	b, c, d			6
	15	Kobayashi (5)		b		a, b	a	c			5
	16	Kobayashi (33)		b		a, b	a	b, c, d			7
	17	Kobayashi (34)	a	b		a, b	a	b, c, d		b	9
	18	Kobayashi (6)				a, b	a	b, c, d			6
	19	Kobayashi (35)				a, b	a	b, c, d			6
	20	Fridman (36)	a	b		a, b	a	b	b	c	8
	21	Beyaert (11)	a			a, b	a	b, c			6
	22	Grumillier (12)	a			a	a	b, c			5
	23	VanVelzen (22)		a		a, b	a, b	b, c			7
	24	Geil (37)				a, b	a	c			5
	25	Chow (38)	a	b	b	a		b, c			6